



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Mark R. Kreitz, Yong S. Jong, Edith Mathiowitz, David J. Enscoe and
Michael J. Bassett

Serial No.: 10/696,829 Art Unit: Not Yet Assigned

Filed: October 30, 2003 Examiner: Not Yet Assigned

For: *NANOPARTICULATE BIOACTIVE AGENTS*

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including three (3) pages of Form PTO-1449 and copies of thirty-three (33) documents cited therein.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

U.S. Patents

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
4,757,128	07-12-1988	Domb, et al.	528/271
4,997,904	03-05-1991	Domb	528/206
5,019,400	05-28-1991	Gombotz, et al.	424/497
5,175,235	12-29-1992	Domb, et al.	528/271
5,271,961	12-21-1993	Mathiowitz, et al.	427/213.31
5,968,972	10-19-1999	Broder, et al.	514/449
5,985,354	11-16-1999	Mathiowitz, et al.	427/2.21
6,143,211	11-07-2000	Mathiowitz, et al.	264/4
6,156,348	12-05-2000	Santos, et al.	424/501
6,197,346	03-06-2001	Mathiowitz, et al.	424/493
6,217,908	04-17-2001	Mathiowitz, et al.	424/493
6,235,224	05-22-2001	Mathiowitz, et al.	264/4
6,235,313	05-22-2001	Mathiowitz, et al.	424/486
6,245,805	06-12-2001	Broder, et al.	514/449
6,262,034	07-17-2001	Mathiowitz, et al.	514/44
6,334,445	01-01-2002	Mettinger	128/898
6,368,586	04-09-2002	Jacob, et al.	424/78.08

Foreign Documents

<u>Number</u>	<u>Publication Date</u>	<u>Patentee</u>	<u>Country</u>
WO 93/21906	11-11-1993	Brown University Research Foundation	PCT
WO 97/15269	05-01-1997	Baker Norton Pharmaceuticals, Inc.	PCT
WO 98/53811	12-03-1998	Baker Norton Pharmaceuticals, Inc.	PCT
WO 00/78247	12-28-2000	Baker Norton Pharmaceuticals, Inc.	PCT
WO 01/30319	05-03-2001	Supergen, Inc.	PCT
WO 01/30448	05-03-2001	Baker Norton Pharmaceuticals, Inc.	PCT
WO 01/57013	08-09-2001	Florida State University Research Foundation	PCT

Publications

BECK, et al., "A new long-acting injectable microcapsule system for the administration of progesterone," *Fertil. & Steril.*, 31(5): 545-55 (1979).

BENITA, et al., "Characterization of Drug-Loaded Poly(*d,l*-lactide) Microspheres," *J. Pharm. Sci.*, 73(12): 1721-24 (1984).

BODMEIER & PAERATAKUL, "Spherical agglomerates of water-insoluble drugs," *J. Pharm. Sci.* 78(11): 964-967 (1989).

GENTA, et al., "Improvement of dexamethasone dissolution rate from spray-dried chitosan micropsheres," *S.T.P. Pharma Sciences* 5(3): 202-207 (1995).

IMAI, et al., "Rapidly absorbed solid oral formulations of ibuprofen using water-soluble gelatin," *J. Pharm. Pharmacol.* 42: 615-619 (1990).

MATHIOWITZ, et al., "Novel microcapsules for delivery systems," *Reactive Polymers*, 6:275-83 (1987).

MATHIOWITZ, et al., "Biologically erodable microspheres as potential oral drug delivery systems," *Nature* 386: 410-414 (1997).


MATHIOWITZ, et al., "Morphology of polyanhydride microsphere delivery systems," *Scanning Microscopy* 4: 329-340 (1990).

WAUGH, et al., "Stability, compatibility, and plasticizer extraction of taxol (NSC-125973) injection diluted in infusion solutions and stored in various containers," *Am. J. Hosp. Pharm.* 48: 1520-1524 (1991).

Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'Patrea L. Pabst', written over a horizontal line.

Patrea L. Pabst
Reg. No. 31,284

Dated: March 3, 2004

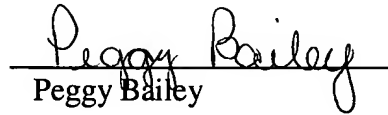
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U.S.S.N.: 10/696,829
Filed: October 30, 2003
INFORMATION DISCLOSURE STATEMENT

Certificate of Mailing under 37 C.F.R. § 1.8(a)

I hereby certify that this Information Disclosure Statement, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: March 3, 2004


Peggy Bailey

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete If Known

Application Number	10/696,829
Filing Date	October 30, 2003
First Named Inventor	Mark R. Kretz
Group Art Unit	
Examiner Name	
Attorney Docket Number	SPS 102/105

Sheet 1 of 3

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		4,757,128		Domb, et al.	07-12-1988	
		4,997,904		Domb	03-05-1991	
		5,019,400		Gombotz, et al.	05-28-1991	
		5,175,235		Domb, et al.	12-29-1992	
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		5,968,972		Broder, et al.	10-19-1999	
		5,985,354		Mathiowitz, et al.	11-16-1999	
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		6,156,348		Santos, et al.	12-05-2000	
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		6,217,908		Mathiowitz, et al.	04-17-2001	
		6,235,224		Mathiowitz, et al.	05-22-2001	
		6,235,313		Mathiowitz, et al.	05-22-2001	
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FOREIGN PATENT DOCUMENTS

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		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
		PCT	WO 93/21906		Brown University Research Foundation	11-11-1993		
		PCT	WO 97/15269		Baker Norton Pharmaceuticals, Inc.	05-01-1997		
		PCT	WO 98/53811		Baker Norton Pharmaceuticals, Inc.	12-03-1998		

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		PCT	WO 01/57013		Florida State University Research Foundation	08-09-2001		

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		Group Art Unit			
		Examiner Name			
Sheet	3	of	3	Attorney Docket Number	SPS 102/105

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		BECK, et al., "A new long-acting injectable microcapsule system for the administration of progesterone," <i>Fertil. & Steril.</i> , 31(5): 545-55 (1979).	
		BENITA, et al., "Characterization of Drug-Loaded Poly(D,Lactide) Microspheres," <i>J. Pharm. Sci.</i> , 73(12): 1721-24 (1984).	
		BODMEIER & PAERATAKUL, "Spherical agglomerates of water-insoluble drugs," <i>J. Pharm. Sci.</i> 78(11): 964-967 (1989).	
		GENTA, et al., "Improvement of dexamethasone dissolution rate from spray-dried chitosan micropsheres," <i>S.T.P. Pharma Sciences</i> 5(3): 202-207 (1995).	
		IMAI, et al., "Rapidly absorbed solid oral formulations of ibuprofen using water-soluble gelatin," <i>J. Pharm. Pharmacol.</i> 42: 615-619 (1990).	
		MATHIOWITZ, et al., "Novel microcapsules for delivery systems," <i>Reactive Polymers</i> , 6:275-83 (1987).	
		MATHIOWITZ, et al., "Biologically erodable microspheres as potential oral drug delivery systems," <i>Nature</i> 386: 410-414 (1997).	
		MATHIOWITZ, et al., "Morphology of polyanhydride microsphere delivery systems," <i>Scanning Microscopy</i> 4: 329-340 (1990).	
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